

31 October 2017  
EMA/339594/2016 Rev.3  
Human Medicines Evaluation

[The timetables in this document may be subject to revision](#)

## Initial (Full) Marketing Authorisation application accelerated assessment timetables<sup>†</sup>

[Assessment of initial submission \(90-day timetable\)](#)

[Assessment of responses to List of Questions \(30-day timetable after clock-stop for submission of responses\)](#)

[Assessment of responses to List of Questions \(30-day timetable after immediate responses\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after immediate responses\)](#)

(<sup>†</sup>) This timetable is not applicable to Advanced Therapy Medicinal Products (ATMPs); for these the applicant should refer to the timetable for initial Marketing Authorisation applications for ATMPs.

## Assessment of initial submission (90-day timetable)

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	PRAC outcome	Early draft LOQ (for Peer review tele-conference)	Peer review tele-conference (TC)	Draft LoQ	List of Questions (LoQ) (~) (#)	Opinion (#)
A1	03/01/2017	20/01/2017	22/03/2017	29/03/2017	01/04/2017	01/04/2017	06/04/2017	07/04/2017	10/04/2017	13/04/2017	19/04/2017	21/04/2017
A2	30/01/2017	16/02/2017	18/04/2017	25/04/2017	28/04/2017	28/04/2017	05/05/2017	05/05/2017	08/05/2017	11/05/2017	16/05/2017	18/05/2017
A3	06/03/2017	23/03/2017	23/05/2017	30/05/2017	02/06/2017	02/06/2017	09/06/2017	09/06/2017	12/06/2017	15/06/2017	20/06/2017	22/06/2017
A4	31/03/2017	20/04/2017	20/06/2017	27/06/2017	30/06/2017	30/06/2017	06/07/2017	07/07/2017	10/07/2017	13/07/2017	18/07/2017	20/07/2017
A5												
A6	29/05/2017	15/06/2017	15/08/2017	22/08/2017	25/08/2017	25/08/2017	01/09/2017	01/09/2017	04/09/2017	07/09/2017	12/09/2017	14/09/2017
A7	26/06/2017	13/07/2017	12/09/2017	19/09/2017	22/09/2017	22/09/2017	28/09/2017	29/09/2017	02/10/2017	05/10/2017	10/10/2017	12/10/2017
A8	24/07/2017	10/08/2017	10/10/2017	17/10/2017	20/10/2017	20/10/2017	26/10/2017	27/10/2017	30/10/2017	03/11/2017	07/11/2017	09/11/2017
A9	25/08/2017	14/09/2017	14/11/2017	21/11/2017	24/11/2017	24/11/2017	30/11/2017	01/12/2017	04/12/2017	07/12/2017	12/12/2017	14/12/2017
A10	09/10/2017	26/10/2017	22/12/2017	03/01/2018	05/01/2018	05/01/2018	11/01/2018	12/01/2018	15/01/2018	18/01/2018	23/01/2018	25/01/2018
A11	06/11/2017	23/11/2017	23/01/2018	30/01/2018	02/02/2018	02/02/2018	08/02/2018	09/02/2018	12/02/2018	15/02/2018	20/02/2018	22/02/2018
A12												
A13	08/01/2018	25/01/2018	27/03/2018	03/04/2018	06/04/2018	06/04/2018	12/04/2018	13/04/2018	16/04/2018	19/04/2018	24/04/2018	26/04/2018
A14	12/02/2018	01/03/2018	02/05/2018	08/05/2018	14/05/2018	14/05/2018	17/05/2018	18/05/2018	21/05/2018	24/05/2018	29/05/2018	31/05/2018
A15	11/03/2018	29/03/2018	29/05/2018	05/06/2018	08/06/2018	08/06/2018	14/06/2018	15/06/2018	18/06/2018	21/06/2018	26/06/2018	28/06/2018
A16	09/04/2018	26/04/2018	26/06/2018	03/07/2018	06/07/2018	06/07/2018	12/07/2018	13/07/2018	16/07/2018	19/07/2018	24/07/2018	26/07/2018
A17												
A18	04/06/2018	21/06/2018	21/08/2018	28/08/2018	31/08/2018	31/08/2018	06/09/2018	07/09/2018	10/09/2018	13/09/2018	18/09/2018	20/09/2018
A19	02/07/2018	19/07/2018	18/09/2018	25/09/2018	28/09/2018	28/09/2018	04/10/2018	05/10/2018	08/10/2018	11/10/2018	16/10/2018	18/10/2018
A20	30/07/2018	16/08/2018	16/10/2018	23/10/2018	26/10/2018	26/10/2018	31/10/2018	03/11/2018	05/11/2018	08/11/2018	13/11/2018	15/11/2018
A21	27/08/2018	13/09/2018	13/11/2018	20/11/2018	23/11/2018	23/11/2018	29/11/2018	30/11/2018	03/12/2018	06/12/2018	11/12/2018	13/12/2018
A22	15/10/2018	01/11/2018	03/01/2019	08/01/2019	11/01/2019	11/01/2019	17/01/2019	18/01/2019	21/01/2019	24/01/2019	29/01/2019	31/01/2019
A23	12/11/2018	29/11/2018	29/01/2019	05/02/2019	08/02/2019	08/02/2019	14/02/2019	15/02/2019	18/02/2019	21/02/2019	26/02/2019	28/02/2019
A24												
A25	08/01/2019	25/01/2019	26/03/2019	02/04/2019	05/04/2019	05/04/2019	11/04/2019	12/04/2019	15/04/2019	17/04/2019	24/04/2019	26/04/2019

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	PRAC outcome	Early draft LOQ (for Peer review tele-conference)	Peer review telecon-ference (TC)	Draft LoQ	List of Questions (LoQ) (~) (#)	Opinion (#)
A26	10/02/2019	27/02/2019	30/04/2019	06/05/2019	10/05/2019	10/05/2019	16/05/2019	16/05/2019	20/05/2019	23/05/2019	27/05/2019	29/05/2019
A27	11/03/2019	28/03/2019	28/05/2019	04/06/2019	07/06/2019	07/06/2019	14/06/2019	14/06/2019	17/06/2019	20/06/2019	25/06/2019	27/06/2019
A28	08/04/2019	25/04/2019	25/06/2019	02/07/2019	05/07/2019	05/07/2019	11/07/2019	12/07/2019	15/07/2019	18/07/2019	23/07/2019	25/07/2019
A29												
A30	03/06/2019	20/06/2019	20/08/2019	27/08/2019	30/08/2019	30/08/2019	05/09/2019	06/09/2019	09/09/2019	12/09/2019	17/09/2019	19/09/2019
A31	01/07/2019	18/07/2019	17/09/2019	24/09/2019	27/09/2019	27/09/2019	03/10/2019	04/10/2019	07/10/2019	10/10/2019	15/10/2019	17/10/2019
A32	29/07/2019	15/08/2019	15/10/2019	22/10/2019	25/10/2019	25/10/2019	31/10/2019	31/10/2019	04/11/2019	07/11/2019	12/11/2019	14/11/2019
A33	23/08/2019	12/09/2019	12/11/2019	19/11/2019	22/11/2019	22/11/2019	28/11/2019	29/11/2019	02/12/2019	05/12/2019	10/12/2019	12/12/2019
A34	14/10/2019	31/10/2019	03/01/2020	08/01/2020	10/01/2020	10/01/2020	16/01/2020	17/01/2020	20/01/2020	23/01/2020	28/01/2020	30/01/2020
A35	11/11/2019	28/11/2019	28/01/2020	04/02/2020	07/02/2020	07/02/2020	13/02/2020	14/02/2020	17/02/2020	20/02/2020	25/02/2020	27/02/2020
A36												
A37	13/01/2020	30/01/2020	31/03/2020	07/04/2020	08/04/2020	08/04/2020	17/04/2020	17/04/2020	20/04/2020	23/04/2020	28/04/2020	30/04/2020
A38	10/02/2020	27/02/2020	28/04/2020	05/05/2020	08/05/2020	08/05/2020	14/05/2020	15/05/2020	18/05/2020	20/05/2020	26/05/2020	28/05/2020
A39	09/03/2020	26/03/2020	26/05/2020	02/06/2020	05/06/2020	05/06/2020	11/06/2020	12/06/2020	15/06/2020	18/06/2020	23/06/2020	25/06/2020
A40	01/04/2020	23/04/2020	23/06/2020	30/06/2020	03/07/2020	03/07/2020	09/07/2020	10/07/2020	13/07/2020	16/07/2020	21/07/2020	23/07/2020
A41												
A42	29/05/2020	18/06/2020	18/08/2020	25/08/2020	28/08/2020	28/08/2020	04/09/2020	04/09/2020	07/09/2020	10/09/2020	15/09/2020	17/09/2020
A43	29/06/2020	16/07/2020	15/09/2020	22/09/2020	25/09/2020	25/09/2020	01/10/2020	02/10/2020	05/10/2020	08/10/2020	13/10/2020	15/10/2020
A44	27/07/2020	13/08/2020	13/10/2020	20/10/2020	23/10/2020	23/10/2020	29/10/2020	30/10/2020	03/11/2020	05/11/2020	10/11/2020	12/11/2020
A45	24/08/2020	10/09/2020	10/11/2020	17/11/2020	20/11/2020	20/11/2020	26/11/2020	27/11/2020	30/11/2020	03/12/2020	08/12/2020	10/12/2020
A46	12/10/2020	29/10/2020	04/01/2021	07/01/2021	08/01/2021	08/01/2021	14/01/2021	15/01/2021	18/01/2021	21/01/2021	26/01/2021	28/01/2021
A47	09/11/2020	26/11/2020	26/01/2021	02/02/2021	05/02/2021	05/02/2021	11/02/2021	12/02/2021	15/02/2021	18/02/2021	23/02/2021	25/02/2021
A48												
A49	04/01/2021	21/01/2021	23/03/2021	30/03/2021	31/03/2021	31/03/2021	09/04/2021	09/04/2021	12/04/2021	15/04/2021	20/04/2021	22/04/2021
A50	01/02/2021	18/02/2021	20/04/2021	27/04/2021	30/04/2021	30/04/2021	06/05/2021	07/05/2021	10/05/2021	12/05/2021	18/05/2021	20/05/2021
A51	08/03/2021	25/03/2021	25/05/2021	01/06/2021	04/06/2021	04/06/2021	10/06/2021	11/06/2021	14/06/2021	17/06/2021	22/06/2021	24/06/2021
A52	05/04/2021	22/04/2021	22/06/2021	29/06/2021	02/07/2021	02/07/2021	08/07/2021	09/07/2021	12/07/2021	15/07/2021	20/07/2021	22/07/2021

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	PRAC outcome	Early draft LOQ (for Peer review tele-conference)	Peer review telecon-ference (TC)	Draft LoQ	List of Questions (LoQ) (~) (#)	Opinion (#)
A53												
A54	31/05/2021	17/06/2021	17/08/2021	24/08/2021	27/08/2021	27/08/2021	03/09/2021	03/09/2021	06/09/2021	09/09/2021	14/09/2021	16/09/2021
A55	28/06/2021	15/07/2021	14/09/2021	21/09/2021	24/09/2021	24/09/2021	30/09/2021	01/10/2021	04/10/2021	07/10/2021	12/10/2021	14/10/2021
A56	26/07/2021	12/08/2021	12/10/2021	19/10/2021	22/10/2021	22/10/2021	28/10/2021	29/10/2021	29/10/2021	04/11/2021	09/11/2021	11/11/2021
A57	27/08/2021	16/09/2021	16/11/2021	23/11/2021	26/11/2021	26/11/2021	02/12/2021	03/12/2021	06/12/2021	09/12/2021	14/12/2021	16/12/2021

(\*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(^) The validation period between submission date and start date is thirteen EMA working days. For further information about the dates on which the Agency will be closed during the current year, please refer to the business hours and holidays page on the website.

(\*\*) Comments from CHMP and PRAC members are not made available to Applicants.

(~) The accelerated assessment timetable could be reverted to a regular one at the time of the List of Questions and at the judgement of the CHMP. In such a case, the assessment of the responses to the List of Questions will follow the regular 60-day timetable foreseen for initial Marketing authorisation applications, to which the applicant should refer, and the remainder of this timetable will no longer apply.

(#) A List of Question or an Opinion will be adopted at the end of the first assessment phase. An Opinion is adopted on the last day of the CHMP and concludes the assessment procedure. Alternatively, a List of Questions is adopted on the second day of the CHMP meeting.

## Assessment of responses to List of Questions (LOQ) <sup>7</sup>

30-day timetable after clock-stop for submission of responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
B1	20/01/2017	23/01/2017	09/02/2017	14/02/2017	16/02/2017	21/02/2017	23/02/2017
B2	17/02/2017	20/02/2017	09/03/2017	14/03/2017	16/03/2017	21/03/2017	23/03/2017
B3	17/03/2017	21/03/2017	06/04/2017	10/04/2017	12/04/2017	19/04/2017	21/04/2017
B4	14/04/2017	17/04/2017	04/05/2017	08/05/2017	11/05/2017	16/05/2017	18/05/2017
B5	19/05/2017	22/05/2017	08/06/2017	13/06/2017	15/06/2017	20/06/2017	22/06/2017
B6	16/06/2017	19/06/2017	06/07/2017	11/07/2017	13/07/2017	18/07/2017	20/07/2017
B7							
B8	11/08/2017	14/08/2017	31/08/2017	05/09/2017	07/09/2017	12/09/2017	14/09/2017
B9	08/09/2017	11/09/2017	28/09/2017	03/10/2017	05/10/2017	10/10/2017	12/10/2017
B10	06/10/2017	09/10/2017	27/10/2017	31/10/2017	03/11/2017	07/11/2017	09/11/2017
B11	10/11/2017	13/11/2017	30/11/2017	05/12/2017	07/12/2017	12/12/2017	14/12/2017
B12	22/12/2017	25/12/2017	11/01/2018	16/01/2018	18/01/2018	23/01/2018	25/01/2018
B13	19/01/2018	22/01/2018	08/02/2018	13/02/2018	15/02/2018	20/02/2018	22/02/2018
B14	16/02/2018	19/02/2018	08/03/2018	13/03/2018	15/03/2018	20/03/2018	22/03/2018
B15	23/03/2018	26/03/2018	12/04/2018	17/04/2018	19/04/2018	24/04/2018	26/04/2018
B16	27/04/2018	30/04/2018	17/05/2018	22/05/2018	24/05/2018	29/05/2018	31/05/2018
B17	25/05/2018	28/05/2018	14/06/2018	19/06/2018	21/06/2018	26/06/2018	28/06/2018
B18	22/06/2018	25/06/2018	12/07/2018	17/07/2018	19/07/2018	24/07/2018	26/07/2018
B19							
B20	17/08/2018	20/08/2018	06/09/2018	11/09/2018	13/09/2018	18/09/2018	20/09/2018
B21	14/09/2018	17/09/2018	04/10/2018	09/10/2018	11/10/2018	16/10/2018	18/10/2018
B22	12/10/2018	15/10/2018	31/10/2018	06/11/2018	08/11/2018	13/11/2018	15/11/2018
B23	09/11/2018	12/11/2018	29/11/2018	04/12/2018	06/12/2018	11/12/2018	13/12/2018
B24	21/12/2018	31/12/2018	17/01/2019	22/01/2019	24/01/2019	29/01/2019	31/01/2019
B25	25/01/2019	28/01/2019	14/02/2019	19/02/2019	21/02/2019	26/02/2019	28/02/2019
B26	22/02/2019	25/02/2019	14/03/2019	19/03/2019	21/03/2019	26/03/2019	28/03/2019
B27	25/03/2019	26/03/2019	11/04/2019	15/04/2019	17/04/2019	24/04/2019	26/04/2019
B28	26/04/2019	28/04/2019	16/05/2019	21/05/2019	23/05/2019	27/05/2019	29/05/2019
B29	24/05/2019	27/05/2019	13/06/2019	18/06/2019	20/06/2019	25/06/2019	27/06/2019
B30	21/06/2019	24/06/2019	11/07/2019	16/07/2019	18/07/2019	23/07/2019	25/07/2019
B31							
B32	16/08/2019	19/08/2019	05/09/2019	10/09/2019	12/09/2019	17/09/2019	19/09/2019
B33	13/09/2019	16/09/2019	03/10/2019	08/10/2019	10/10/2019	15/10/2019	17/10/2019
B34	11/10/2019	14/10/2019	31/10/2019	05/11/2019	07/11/2019	12/11/2019	14/11/2019
B35	08/11/2019	11/11/2019	28/11/2019	03/12/2019	05/12/2019	10/12/2019	12/12/2019
B36	23/12/2019	30/12/2019	16/01/2020	21/01/2020	23/01/2020	28/01/2020	30/01/2020
B37	24/01/2020	27/01/2020	13/02/2020	18/02/2020	20/02/2020	25/02/2020	27/02/2020
B38	21/02/2020	24/02/2020	12/03/2020	17/03/2020	19/03/2020	24/03/2020	26/03/2020
B39	27/03/2020	30/03/2020	16/04/2020	21/04/2020	23/04/2020	28/04/2020	30/04/2020
B40	24/04/2020	27/04/2020	14/05/2020	18/05/2020	20/05/2020	26/05/2020	28/05/2020
B41	20/05/2020	25/05/2020	11/06/2020	16/06/2020	18/06/2020	23/06/2020	25/06/2020
B42	19/06/2020	22/06/2020	09/07/2020	14/07/2020	16/07/2020	21/07/2020	23/07/2020
B43							

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (-)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
B44	14/08/2020	17/08/2020	03/09/2020	08/09/2020	10/09/2020	15/09/2020	17/09/2020
B45	11/09/2020	14/09/2020	01/10/2020	06/10/2020	08/10/2020	13/10/2020	15/10/2020
B46	09/10/2020	12/10/2020	29/10/2020	03/11/2020	05/11/2020	10/11/2020	12/11/2020
B47	06/11/2020	09/11/2020	26/11/2020	01/12/2020	03/12/2020	08/12/2020	10/12/2020
B48	23/12/2020	28/12/2020	14/01/2021	19/01/2021	21/01/2021	26/01/2021	28/01/2021
B49	22/01/2021	25/01/2021	11/02/2021	16/02/2021	18/02/2021	23/02/2021	25/02/2021
B50	19/02/2021	22/02/2021	11/03/2021	16/03/2021	18/03/2021	23/03/2021	25/03/2021
B51	19/03/2021	22/03/2021	08/04/2021	13/04/2021	15/04/2021	20/04/2021	22/04/2021
B52	16/04/2021	19/04/2021	06/05/2021	10/05/2021	12/05/2021	18/05/2021	20/05/2021
B53	21/05/2021	24/05/2021	10/06/2021	15/06/2021	17/06/2021	22/06/2021	24/06/2021
B54	18/06/2021	21/06/2021	08/07/2021	13/07/2021	15/07/2021	20/07/2021	22/07/2021
B55							
B56	13/08/2021	16/08/2021	02/09/2021	07/09/2021	09/09/2021	14/09/2021	16/09/2021
B57	10/09/2021	13/09/2021	30/09/2021	05/10/2021	07/10/2021	12/10/2021	14/10/2021
B58	08/10/2021	11/10/2021	28/10/2021	03/11/2021	05/11/2021	09/11/2021	11/11/2021
B59	12/11/2021	15/11/2021	02/12/2021	07/12/2021	09/12/2021	14/12/2021	16/12/2021

(-) For the assessment of responses to a List of Questions a 30-day timetable with or without clockstop (immediate responses) could apply depending on the applicant's ability to provide responses within 5 days and the CHMP and PRAC Rapporteur's capacity to assess them with a timeframe shorter than 30 days.

(\*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(\*\*) Comments from CHMP and PRAC members are not made available to Applicants.

(-) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the updated CHMP and PRAC Rapporteur joint assessment report.

(^) The accelerated assessment timetable could still be reverted to a regular one at the time of the List of Outstanding Issues (LoOI) and at the judgement of the CHMP. In such a case, the assessment of the responses to the LoOI will follow the 60-day timetable foreseen for the responses to the List of Questions for initial Marketing authorisation applications, to which the applicant should refer, and the remainder of this timetable will no longer apply.

(#) List of Questions and Opinion are alternative outcomes adopted on the second or last day of the CHMP meeting, respectively.

## Assessment of responses to List of Questions (LOQ)<sup>7</sup>

30-day timetable after immediate responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
B1	24/01/2017	25/01/2017	09/02/2017	14/02/2017	16/02/2017	21/02/2017	23/02/2017
B2	21/02/2017	22/02/2017	09/03/2017	14/03/2017	16/03/2017	21/03/2017	23/03/2017
B3	22/03/2017	23/03/2017	06/04/2017	10/04/2017	12/04/2017	19/04/2017	21/04/2017
B4	18/04/2017	19/04/2017	04/05/2017	08/05/2017	11/05/2017	16/05/2017	18/05/2017
B5	23/05/2017	24/05/2017	08/06/2017	13/06/2017	15/06/2017	20/06/2017	22/06/2017
B6	20/06/2017	21/06/2017	06/07/2017	11/07/2017	13/07/2017	18/07/2017	20/07/2017
B7							
B8							
B9	12/09/2017	13/09/2017	28/09/2017	03/10/2017	05/10/2017	10/10/2017	12/10/2017
B10	10/10/2017	11/10/2017	27/10/2017	31/10/2017	03/11/2017	07/11/2017	09/11/2017
B11	14/11/2017	15/11/2017	30/11/2017	05/12/2017	07/12/2017	12/12/2017	14/12/2017
B12	22/12/2017	27/12/2017	11/01/2018	16/01/2018	18/01/2018	23/01/2018	25/01/2018
B13	23/01/2018	24/01/2018	08/02/2018	13/02/2018	15/02/2018	20/02/2018	22/02/2018
B14	20/02/2018	21/02/2018	08/03/2018	13/03/2018	15/03/2018	20/03/2018	22/03/2018
B15	27/03/2018	28/03/2018	12/04/2018	17/04/2018	19/04/2018	24/04/2018	26/04/2018
B16	30/04/2018	02/05/2018	17/05/2018	22/05/2018	24/05/2018	29/05/2018	31/05/2018
B17	29/05/2018	30/05/2018	14/06/2018	19/06/2018	21/06/2018	26/06/2018	28/06/2018
B18	26/06/2018	27/06/2018	12/07/2018	17/07/2018	19/07/2018	24/07/2018	26/07/2018
B19							
B20							
B21	18/09/2018	19/09/2018	04/10/2018	09/10/2018	11/10/2018	16/10/2018	18/10/2018
B22	16/10/2018	17/10/2018	31/10/2018	06/11/2018	08/11/2018	13/11/2018	15/11/2018
B23	13/11/2018	14/11/2018	29/11/2018	04/12/2018	06/12/2018	11/12/2018	13/12/2018
B24	07/01/2019	08/01/2019	17/01/2019	22/01/2019	24/01/2019	29/01/2019	31/01/2019
B25	04/02/2019	05/02/2019	14/02/2019	19/02/2019	21/02/2019	26/02/2019	28/02/2019
B26	04/03/2019	05/03/2019	14/03/2019	19/03/2019	21/03/2019	26/03/2019	28/03/2019
B27	02/04/2019	03/04/2019	11/04/2019	15/04/2019	17/04/2019	24/04/2019	26/04/2019
B28	03/05/2019	06/05/2019	16/05/2019	21/05/2019	23/05/2019	27/05/2019	29/05/2019
B29	03/06/2019	04/06/2019	13/06/2019	18/06/2019	20/06/2019	25/06/2019	27/06/2019
B30	01/07/2019	02/07/2019	11/07/2019	16/07/2019	18/07/2019	23/07/2019	25/07/2019
B31							
B32							
B33	23/09/2019	24/09/2019	03/10/2019	08/10/2019	10/10/2019	15/10/2019	17/10/2019
B34	21/10/2019	22/10/2019	31/10/2019	05/11/2019	07/11/2019	12/11/2019	14/11/2019
B35	18/11/2019	19/11/2019	28/11/2019	03/12/2019	05/12/2019	10/12/2019	12/12/2019
B36	06/01/2020	07/01/2020	16/01/2020	21/01/2020	23/01/2020	28/01/2020	30/01/2020
B37	03/02/2020	04/02/2020	13/02/2020	18/02/2020	20/02/2020	25/02/2020	27/02/2020
B38	02/03/2020	03/03/2020	12/03/2020	17/03/2020	19/03/2020	24/03/2020	26/03/2020
B39	06/04/2020	07/04/2020	16/04/2020	21/04/2020	23/04/2020	28/04/2020	30/04/2020
B40	04/05/2020	05/05/2020	14/05/2020	18/05/2020	20/05/2020	26/05/2020	28/05/2020
B41	29/05/2020	02/06/2020	11/06/2020	16/06/2020	18/06/2020	23/06/2020	25/06/2020
B42	29/06/2020	30/06/2020	09/07/2020	14/07/2020	16/07/2020	21/07/2020	23/07/2020
B43							
B44							
B45	21/09/2020	22/09/2020	01/10/2020	06/10/2020	08/10/2020	13/10/2020	15/10/2020

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
B46	19/10/2020	20/10/2020	29/10/2020	03/11/2020	05/11/2020	10/11/2020	12/11/2020
B47	16/11/2020	17/11/2020	26/11/2020	01/12/2020	03/12/2020	08/12/2020	10/12/2020
B48	04/01/2021	05/01/2021	14/01/2021	19/01/2021	21/01/2021	26/01/2021	28/01/2021
B49	01/02/2021	02/02/2021	11/02/2021	16/02/2021	18/02/2021	23/02/2021	25/02/2021
B50	01/03/2021	02/03/2021	11/03/2021	16/03/2021	18/03/2021	23/03/2021	25/03/2021
B51	29/03/2021	30/03/2021	08/04/2021	13/04/2021	15/04/2021	20/04/2021	22/04/2021
B52	26/04/2021	27/04/2021	06/05/2021	10/05/2021	12/05/2021	18/05/2021	20/05/2021
B53	31/05/2021	01/06/2021	10/06/2021	15/06/2021	17/06/2021	22/06/2021	24/06/2021
B54	28/06/2021	29/06/2021	08/07/2021	13/07/2021	15/07/2021	20/07/2021	22/07/2021
B55							
B56							
B57	20/09/2021	21/09/2021	30/09/2021	05/10/2021	07/10/2021	12/10/2021	14/10/2021
B58	18/10/2021	19/10/2021	28/10/2021	03/11/2021	05/11/2021	09/11/2021	11/11/2021
B59	22/11/2021	23/11/2021	02/12/2021	07/12/2021	09/12/2021	14/12/2021	16/12/2021

(~) For the assessment of responses to a List of Questions a 30-day timetable with or without clockstop (immediate responses) could apply depending on the applicant's ability to provide responses within 5 days and the CHMP and PRAC Rapporteur's capacity to assess them with a timeframe shorter than 30 days.

(\*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(\*\*) Comments from CHMP and PRAC members are not made available to Applicants.

(-) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the updated CHMP and PRAC Rapporteur joint assessment report.

(^) The accelerated assessment timetable could still be reverted to a regular one at the time of the List of Outstanding Issues (LoOI) and at the judgement of the CHMP. In such a case, the assessment of the responses to the LoOI will follow the 60-day timetable foreseen for the responses to the List of Questions for initial Marketing authorisation applications, to which the applicant should refer, and the remainder of this timetable will no longer apply.

(#) List of Questions and Opinion are alternative outcomes adopted on the second or last day of the CHMP meeting, respectively.



# Assessment of responses to List of Outstanding Issues (LoOI) <sup>7</sup>

30-day timetable after immediate responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion(^)
D1	24/01/2017	01/02/2017	09/02/2017	14/02/2017	16/02/2017	23/02/2017
D2	21/02/2017	01/03/2017	09/03/2017	14/03/2017	16/03/2017	23/03/2017
D3	29/03/2017	30/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
D4	25/04/2017	26/04/2017	04/05/2017	08/05/2017	11/05/2017	18/05/2017
D5	23/05/2017	31/05/2017	08/06/2017	13/06/2017	15/06/2017	22/06/2017
D6	27/06/2017	28/06/2017	06/07/2017	11/07/2017	13/07/2017	20/07/2017
D7						
D8						
D9	19/09/2017	20/09/2017	28/09/2017	03/10/2017	05/10/2017	12/10/2017
D10	17/10/2017	18/10/2017	27/10/2017	31/10/2017	03/11/2017	09/11/2017
D11	14/11/2017	22/11/2017	30/11/2017	05/12/2017	07/12/2017	14/12/2017
D12	19/12/2017	03/01/2018	11/01/2018	16/01/2018	18/01/2018	25/01/2018
D13	30/01/2018	31/01/2018	08/02/2018	13/02/2018	15/02/2018	22/02/2018
D14	27/02/2018	28/02/2018	08/03/2018	13/03/2018	15/03/2018	22/03/2018
D15	27/03/2018	04/04/2018	12/04/2018	17/04/2018	19/04/2018	26/04/2018
D16	30/04/2018	09/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
D17	05/06/2018	06/06/2018	14/06/2018	19/06/2018	21/06/2018	28/06/2018
D18	03/07/2018	04/07/2018	12/07/2018	17/07/2018	19/07/2018	26/07/2018
D19						
D20						
D21	25/09/2018	26/09/2018	04/10/2018	09/10/2018	11/10/2018	18/10/2018
D22	23/10/2018	24/10/2018	31/10/2018	06/11/2018	08/11/2018	15/11/2018
D23	20/11/2018	21/11/2018	29/11/2018	04/12/2018	06/12/2018	13/12/2018
D24	08/01/2019	09/01/2019	17/01/2019	22/01/2019	24/01/2019	31/01/2019
D25	05/02/2019	06/02/2019	14/02/2019	19/02/2019	21/02/2019	28/02/2019
D26	05/03/2019	06/03/2019	14/03/2019	19/03/2019	21/03/2019	28/03/2019
D27	03/04/2019	04/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
D28	06/05/2019	07/05/2019	16/05/2019	21/05/2019	23/05/2019	29/05/2019
D29	04/06/2019	05/06/2019	13/06/2019	18/06/2019	20/06/2019	27/06/2019
D30	02/07/2019	03/07/2019	11/07/2019	16/07/2019	18/07/2019	25/07/2019
D31						
D32						
D33	24/09/2019	25/09/2019	03/10/2019	08/10/2019	10/10/2019	17/10/2019
D34	22/10/2019	23/10/2019	31/10/2019	05/11/2019	07/11/2019	14/11/2019
D35	19/11/2019	20/11/2019	28/11/2019	03/12/2019	05/12/2019	12/12/2019
D36	07/01/2020	08/01/2020	16/01/2020	21/01/2020	23/01/2020	30/01/2020
D37	04/02/2020	05/02/2020	13/02/2020	18/02/2020	20/02/2020	27/02/2020
D38	03/03/2020	04/03/2020	12/03/2020	17/03/2020	19/03/2020	26/03/2020
D39	07/04/2020	08/04/2020	16/04/2020	21/04/2020	23/04/2020	30/04/2020

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion(^)
D40	05/05/2020	06/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
D41	02/06/2020	03/06/2020	11/06/2020	16/06/2020	18/06/2020	25/06/2020
D42	30/06/2020	01/07/2020	09/07/2020	14/07/2020	16/07/2020	23/07/2020
D43						
D44						
D45	22/09/2020	23/09/2020	01/10/2020	06/10/2020	08/10/2020	15/10/2020
D46	20/10/2020	21/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
D47	17/11/2020	18/11/2020	26/11/2020	01/12/2020	03/12/2020	10/12/2020
D48	05/01/2021	06/01/2021	14/01/2021	19/01/2021	21/01/2021	28/01/2021
D49	02/02/2021	03/02/2021	11/02/2021	16/02/2021	18/02/2021	25/02/2021
D50	02/03/2021	03/03/2021	11/03/2021	16/03/2021	18/03/2021	25/03/2021
D51	30/03/2021	31/03/2021	08/04/2021	13/04/2021	15/04/2021	22/04/2021
D52	27/04/2021	28/04/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
D53	01/06/2021	02/06/2021	10/06/2021	15/06/2021	17/06/2021	24/06/2021
D54	29/06/2021	30/06/2021	08/07/2021	13/07/2021	15/07/2021	22/07/2021
D55						
D56						
D57	21/09/2021	22/09/2021	30/09/2021	05/10/2021	07/10/2021	14/10/2021
D58	19/10/2021	20/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
D59	23/11/2021	24/11/2021	02/12/2021	07/12/2021	09/12/2021	16/12/2021

(-) For the assessment of responses to a List of Outstanding Issues a 30-day timetable with or without clockstop (immediate responses) could apply depending on the applicant's ability to provide responses within 5 days and the CHMP and PRAC Rapporteur's capacity to assess them with the shorter timeframe.

(\*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(\*\*) Comments from CHMP and PRAC members are not made available to Applicants.

(-) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the updated PRAC Rapporteur AR.

(^) The accelerated assessment timetable could still be reverted to a regular one at this time through adoption of a second List of Outstanding Issues (LoOI) and at the judgement of the CHMP. In such a case, the assessment of the responses to the 2nd LoOI can only follow the 60-day timetable foreseen for the responses to the List of Outstanding Issues for initial Marketing authorisation applications, to which the applicant should refer.